The Benefits of EVAR Planning Using a 3D Workstation CME

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WHAT THIS PAPER ADDS

In order to enhance the midterm results of EVAR, and especially the occurrence of type 1 endoleaks, this study shows that endovascular therapists should always perform endograft sizing utilizing 3D workstations.

Objectives: To evaluate the influence of planning endovascular aneurysm repair (EVAR) with a three-dimensional (3D) workstation on early and midterm outcomes.

Methods: All patients undergoing infrarenal EVAR performed between 2006 and 2009 at our institution were included in the current study. Prior to 2008 (group 1), endograft sizing was performed by interrogation of computed tomography angiography axial images. After 2008 (group 2), endograft sizing was routinely performed using a 3D workstation (Aquarius, Terarecon), allowing for multiplanar reconstruction and centerline analysis. Pre-, peri-, postoperative, and follow-up data were prospectively entered in an electronic database. All postoperative complications and subsequent secondary interventions depicted during the 2-year period following EVAR were compared. Secondary intervention and mortality rates were defined at 2 years and compared. Freedom from secondary intervention and overall survival rates were calculated using the Kaplan–Meier method during follow-up and compared by log-rank test.

Results: A total of 295 patients (149 patients in group 1 and 146 patients in group 2) were included. All patients had completed a minimum of 2 years of follow-up. During this 2-year period following EVAR, the type 1 endoleak rate was 8.7% in group 1 and 1.4% in group 2 ($p = .004$) respectively. Secondary intervention rates related to type 1 endoleak was 5.4% in group 1 and 0 in group 2 ($p < .001$). No difference was observed regarding all-cause mortality, aneurysm-related death, and freedom from secondary intervention rates during follow-up.

Conclusion: The routine use of 3D workstations for EVAR planning significantly reduces the rate of type 1 endoleaks and, therefore, the rate of related secondary interventions.

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INTRODUCTION

Endovascular treatment of abdominal aortic aneurysm (EVAR) was introduced 20 years ago.[1] Recent publications have reported reductions in early mortality rates.[2,3] It is generally agreed that the major drawback of EVAR is the high secondary intervention rate required to correct endograft-related complications.[2] The postoperative presence of type 1 or 3 endoleaks (immediate or late), graft limb thrombosis, aneurysm expansion, aneurysm rupture, or conversion to open repair is defined as clinical failure after EVAR.[4] Precise preoperative study of the aortic anatomy based on high-quality preoperative computerized tomography angiography scans (CTA) is required to determine EVAR suitability and to accurately size the endograft and plan the procedure. Endograft sizing software including three-dimensional (3D) reconstructions of the preoperative computed tomography angiography (CTA) and stretch reconstructions perpendicular to a semi-automatically generated centerline are now widely available for endovascular surgeons (Fig. 1). This vessel centerline allows accurate measurement of the vessel length.[5,6] The correlation between procedures planned using dedicated imaging software and the reality of the intraoperative procedure has been studied only in small cohorts.[7] To date, the impact of planning with 3D workstations on early and midterm complications and secondary interventions after EVAR has not been established.

MATERIAL AND METHODS

All patients treated for infrarenal abdominal aortic aneurysm (AAA) using EVAR at our institution from January 2006 to December 2009 were included in the current study. This study period was chosen to ensure a minimum 2-year follow-up period for every patient and to eliminate potential interfering variables such as the use of newer EVAR devices and

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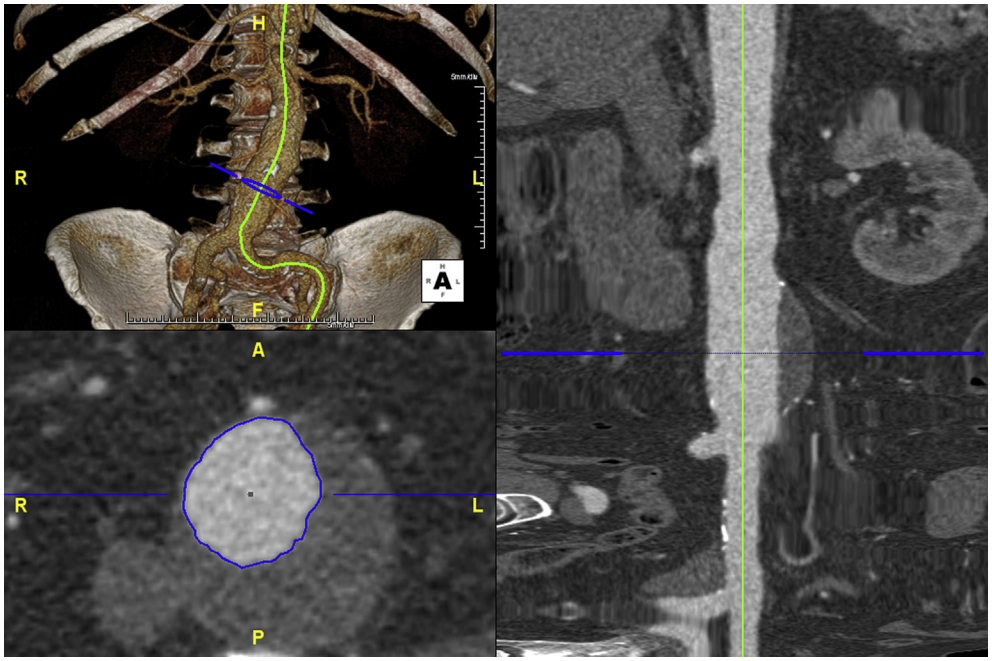

Figure 1. Interface of the Aquarius iNtuition Viewer. The software has semi-automatically generated a "centerline of flow" (CLF); the aorta has been longitudinally stretched along this CLF providing a curved planar reconstruction (CPR).

other technologies. The medical records and images from a prospectively collected database were analyzed retrospectively. Two groups of patients were identified:

- Group 1 (non-3D workstation-assisted sizing): all patients treated prior to January 2008, when preoperative aortic anatomical measurements were performed using axial CTA images only.
- Group 2 (3D workstation-assisted sizing): all patients treated from January 2008, for whom CTA analysis and endograft sizing was always performed with the use of dedicated software on the 3D workstations.

All images were comparable: since 2005, all CTAs have been performed at our institution using a 64-slice CT scanner (Philips Brilliance 64 CT scanner, Philips Healthcare, Amsterdam, the Netherlands). Triple-phase acquisition with unenhanced and contrast-enhanced in arterial (with bolus-tracking) and delayed phases (at 70 seconds) was carried out from the thorax to the femoral bifurcations.

In group 1, preoperative aortic measurements for endograft sizing were estimated by serial examination of the axial CTA images. The axial diameters of the aorta at the level of the lowest renal artery and 15 mm inferior of the aorto-iliac bifurcation and the distal common iliac arteries were measured. The longitudinal distances between the lower margin of the lowest renal artery and the aorto-iliac bifurcation and also between the lower margin of the lowest renal artery and both common iliac bifurcations were approximated by manual scrolling of the axial reconstructions, slice counting, and knowledge of the slice thickness. Where there was uncertainty, the longitudinal distances were confirmed peri-operatively by means of angiography using a graduated intra-aortic measuring catheter (5-Fr Pigtail catheter).

In group 2, the software used for reconstructions was the Aquarius iNtuition Viewer (Aquarius, TeraRecon, San Matteo, CA, USA). A "centerline of flow" reconstruction using a semi-automated centerline algorithm was generated to assess the aortic morphology[8] (Fig. 1). The centerline was manually adjusted when necessary. Measurements included the diameters of the aorta at the level of the lowest renal artery and 15 mm lower, of the aorto-iliac bifurcation, and of the distal common iliac arteries, the longitudinal distances between the lower margin of the lowest renal artery and the aorto-iliac bifurcation and between the lower margin of the lowest renal artery and both common iliac arteries. The diameters measured in this group are the maximal diameter measured within the orthogonal plane, perpendicular to the centerline of flow.

General details corresponding to patient characteristics, anatomic measurements, and surgical data including the type of the implanted endograft and supplementary procedures were collected.

Contrast-enhanced CTA was routinely performed prior to hospital discharge. In patients with poor renal function, contrast-free CT was associated with contrast-enhanced ultrasound examination.[9]

Post-discharge follow-up included an ultrasound examination at 6 months and contrast-enhanced CTA associated with plain abdominal radiography at 12 months; the last two examinations were then repeated annually in the absence of renal function impairment.

All postoperative complications and subsequent secondary interventions depicted during the 2-year period following EVAR were collected according to the method described by Chaikof et al.[4] The delay between the initial procedure and the postoperative complications was noted.

The 30-day mortality rate, the survival and freedom from secondary intervention rates at 1, 2, and 3 years were calculated for each group.

During the study period, the same two surgeons performed all EVAR planning and implantations. Analysis of the postoperative CTAs was performed by a senior vascular radiologist.

Statistical analysis

Statistical analysis was performed using SPSS, version 20.0 (IBM Armonk, NY, USA).

Continuous variables are expressed as median with range or mean ± standard deviation (SD) and categorical data as percentages.

Comparisons between groups were made with *t* tests or Mann–Whitney tests for continuous variables, and with chi-square test for categorical variables.

Life tables according to the Kaplan–Meier method were conducted to estimate survival and freedom from secondary intervention rates, and differences were tested with the log-rank test.

A p value $<.05$ was considered as statistically significant.

RESULTS

Between January 2006 and December 2009, 326 patients with AAA were treated in our institution using standard commercially available endografts. Of these, 295 patients (90.5%) had completed a minimum of 2 years of our standard follow-up program and were included in the current study. Prior to 2008 (group 1 = 149 patients), endograft sizing was performed by an analysis of the preoperative CTA axial cuts. After 2008 (group 2 = 146 patients), endograft sizing was performed using a 3D workstation (Aquarius, Terarecon). Out of the whole study group, 251 (77.4%) received an aorto-bi-iliac endograft and 44 (22.6%) an aorto-uni-iliac device with supplementary femoro-femoral bypass. A total of 287 Zenith (Cook Medical, Bloomington, IN, USA) and eight Talent (Medtronic, Minneapolis, MN, USA) endografts were implanted. Tables 1 and 2 provide a summary of the preoperative characteristics of each group. No significant difference ($p > .05$) was observed in these characteristics between the groups.

Median follow-up was 41.5 months in group 1 (range 24.2–75.2 months) and 36.4 months in group 2 (range 24–50.2 months) ($p < .001$), but this is accounted for by the fact that the group 1 patients were operated on earlier than the group 2 patients.

The 30-day mortality rate was 2.3% (2.0% in group 1, 2.7% in group 2; $p = .68$).

The 1-year, 2-year, and 3-year estimated (Kaplan–Meier method) survival rates were respectively 92.6%, 86%, and 83% in group 1 and 90.4%, 85%, and 82% in group 2 (log-rank, $p = .484$) (Fig. 2A).

A total of 21 deaths were reported in each group during the 2-year follow-up period, of which eight were reported as being aneurysm related (Table 3). There was no statistically significant difference between the groups with respect to aneurysm or procedure related deaths.

Table 1. Demographics, comorbidities, and device specifics.

	Group 1 ($n = 149$)	Group 2 ($n = 146$)	p Value
Age, years (mean ± SD)	72.77 (±8.46)	72.81 (±8.74)	0.968
Male	143 (96%)	139 (95%)	0.784
BMI (kg/m^2)	28.25 (±5.07)	27.54 (±4.74)	0.244
HBP	114 (76%)	112 (77%)	1
Type 2 diabetes	26 (17%)	26 (18%)	1
Coronary disease	63 (42%)	64 (44%)	0.81
COPD	61 (41%)	54 (37%)	0.55
Renal failure	22 (15%)	25 (17%)	0.63
Cardiac failure	4 (3%)	9 (6%)	0.16
Stroke	11 (7%)	18 (12%)	0.17
Device configuration			
Aorto-uni-iliac	27 (18%)	17 (12%)	0.14
Aorto-bi-iliac	122 (82%)	129 (88%)	0.14
Hypogastric embolization	11 (7%)	11 (7%)	0.87

BMI = body mass index; COPD = chronic obstructive pulmonary disease; HBP = high blood pressure; SD = standard deviation.

During the 2-year period following surgery, there were a total of 44 postoperative complications: 27 in group 1 and 17 in group 2 ($p = .941$). These postoperative complications are detailed in Table 4. There was a significantly higher rate of type 1 endoleaks in group 1 (13 (8.7%) versus 2 (1.4%), $p = .004$). Secondary intervention rate for type 1 endoleak in group 1 was consequently statistically more frequent than in group 2 ($p < .001$) (Table 5). The rate of graft-related complications was higher in group 1 (14.8% vs. 8.2%) but it did not reach statistical significance ($p = .0784$). The overall (groups 1 and 2) freedom from secondary intervention rate was 88.8% at 2 years (Fig. 2B). There was no statistical difference between both groups in this regard (86% in group 1 and 91% in group 2; $p = .617$) despite less secondary interventions performed in group 2.

The overall median time to secondary intervention was 17 months (range 0–23.3 months), with a median time of 18 months in group 1 and 15 months in group 2 ($p = .6$).

Table 2. Anatomic data (mm, mean ± standard deviation).

	Group 1	Group 2	p Value
AAA maximum diameter	58.7 ± 11.2	58.2 ± 10.6	0.244
Aortic diameter at the level of the lowest renal artery	25.4 ± 3.6	23.5 ± 3.2	0.123
Aortic diameter 15 mm down to the lowest renal artery	27.4 ± 3.1	24.9 ± 4.1	0.072
Infrarenal neck length	33.4 ± 12.0	32.6 ± 14.8	0.866
Common Iliac diameter at sealing zone	15.4 ± 2.8	15.8 ± 3.1	0.708
Iliac sealing zone length	24.6 ± 5.5	24.8 ± 5.6	0.937

AAA = abdominal aortic aneurysm.

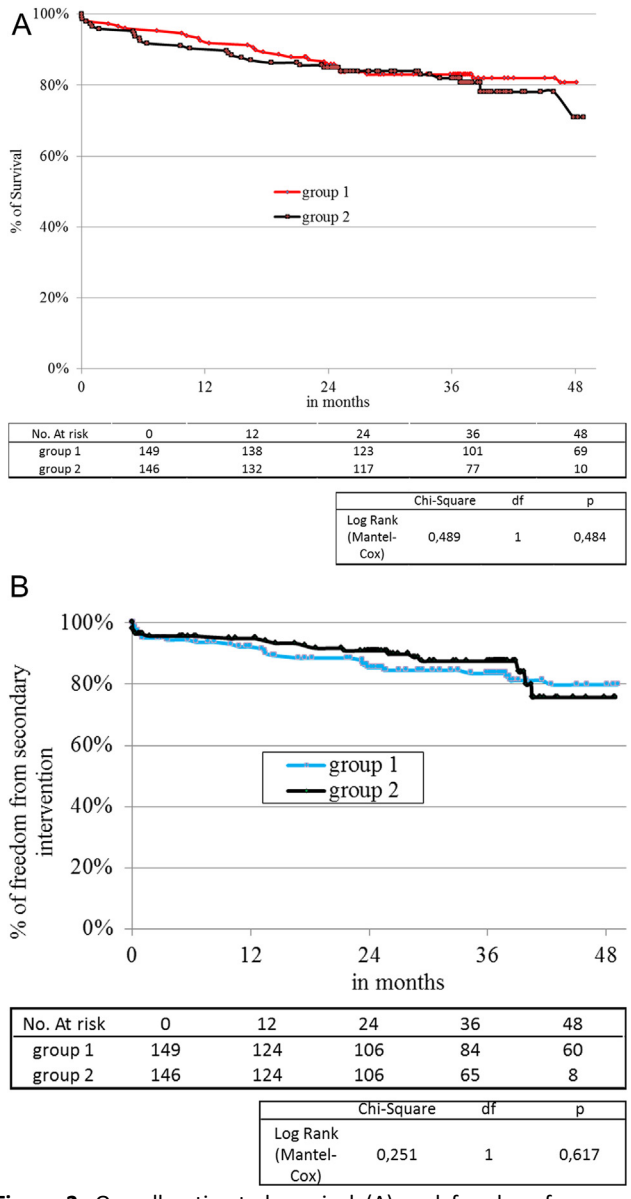

Figure 2. Overall estimated survival (A) and freedom from secondary intervention estimated survival rates (Kaplan–Meier Method) (B).

DISCUSSION

The clinical impact of sizing endografts with a 3D workstation for planning and performing EVAR had not previously been critically evaluated. In our department, the first version of the Aquarius workstation was available towards the close of 2007. We started using the 3D workstation for all EVAR planning in routine practice in January 2008 hoping to gain more information than was available using a "simple" CT scan analysis, by the addition of 3D reformatted CT reconstructions.[10]

In this analysis, we decided to include only those patients with a minimum 24-month follow-up in order to be able to evaluate the impact of planning with a 3D workstation on early and midterm outcomes. That EVAR is associated with a higher secondary arterial intervention rate than open repair has been widely reported.[2] This might impair both patient quality of life[11] and EVAR cost-effectiveness.[12,13] The number of type 1 endoleaks and subsequent secondary intervention rate was significantly higher in group 1 (non-assisted sizing) than in group 2 (3D workstation-assisted sizing). In the EVAR1 trial, the type 1 endoleak (some associated with proximal endograft migration) rate was 8.1% (43 in 529 patients),[14] which is similar to group 1 in this report. The 2-year survival rates (86% in group 1 and 85% in group 2) of our cohort are broadly similar to those reported in the EVAR and DREAM trials.[14,15]

Type 1 endoleaks are high-flow and high-pressure endoleaks and usually require secondary intervention.[16] They result from poor endograft sizing (diameter and/or sealing zone length) or adverse aortic anatomy (i.e. aneurysm neck anatomy unsuitable for EVAR).[4,17] Our study shows clinical evidence that software-assisted sizing is associated with reductions in the incidence of type 1 endoleaks ($p = .004$) and their related secondary interventions ($p < .001$). One previous retrospective study has already demonstrated that the use of a software-assisted centerline (using PEMS, Medical Media System, West Lebanon, NH, USA) reduces the use of unplanned iliac extensions in EVAR procedures.[7]

The implantation of an infrarenal aortic endoprosthesis is a relatively simple procedure. Its execution requires preoperative length and diameter measurements and then accurate longitudinal device placement. Essential information needed for the preoperative assessment of an aortic aneurysm includes the relationship of the aneurysm to the aortic branches, the degree of iliac arterial involvement by the aneurysm, the presence of other coexisting iliac arterial or aortic aneurysms, the presence of supernumerary or aberrant aortic branches, and the presence of coexistent iliac arterial occlusive disease. Software designed to assist EVAR planning using 3D workstations have been developed

Table 3. Aneurysm-related mortality during the 2-year period after endovascular treatment of abdominal aortic aneurysm.

	Group 1 ($n = 149$)		Group 2 ($n = 146$)		p Value
	n	%	n	%	
Early mortality (≤30 days)					
peri-operative hemorrhage	2	1.3	0	0	
acute coronary syndrome	0	0	2	1.4	
sepsis	1	0.7	1	0.7	
Late mortality (>30 days)					
sepsis	0	0	2	1.4	
Total	3	2	5	3.4	0.45

Table 4. All complications depicted during the 2-year period after endovascular treatment of abdominal aortic aneurysm.

	Group 1 ($n = 149$)		Group 2 ($n = 146$)		p Value
	n	%	n	%	
Type 1 endoleaks	13	8.7	2	1.4	0.004
1a (proximal)	6	4.0	0	0	0.01
1b (distal)	7	4.7	2	1.4	0.097
Type 3 endoleaks	2	1.3	1	0.7	[a]
Type 2 endoleaks requiring embolization	2	1.3	2	1.4	[a]
Limb kinking or thrombosis	5	3.3	7	4.8	0.529
All above graft-related complications	22	14.8	12	8.2	0.0784
Renal artery malperfusion	1	0.7	0	0	
Ischemic colitis	1	0.7	0	0	
Aneurysm related mortality	3	2.0	5	3.4	0.45
Total	27	18.1	17	11.6	0.144

[a] When the number of events was less than 5, the p value was considered as not relevant.

Table 5. Secondary Interventions during the first 2 years of follow-up.

	Group 1 ($n = 149$)		Group 2 ($n = 146$)		p Value
	n	%	n	%	
Type 1 endoleak	8	5.4	0	0	$<.001$
1a (proximal)[a]	4		0		[c]
1b (distal)[b]	4		0		[c]
Type 3 endoleak	0	0	1	0.7	[c]
Type 2 endoleak	2	1.3	3	2	[c]
Limb kinking or thrombosis	5	3.3	7	4.8	.529
Femoral Access repair	3	2	1	0.7	[c]
Ischemic colitis	1	0.7	0	0	[c]
Renal artery stenting	1	0.7	0	0	[c]
Total	18	12.1	12	8.2	.271

[a] Proximal aortic cuff extension.
[b] Distal limb extension.
[c] When the number of events was less than 5, the p value was considered as not relevant.

during the past 10 years. On currently available 3D workstations, automated and semi-automated vessel analysis tools are integrated in the software. The generation of a centerline of flow image (Fig. 1) allows the visualization of a tortuous aorta as though it were straightened and greatly aids in the design of the endoprosthesis, particularly in accurately measuring the correct length of the graft between key anatomic targets such as branch locations and vessel bifurcations.[5,6,18] Nevertheless, a degree of judgment by the planner/operator is required.

Multidetector row CT and 3D workstation analysis have now replaced the old "gold standard" intra-arterial digital subtraction angiography for assessing (the length of) abdominal, thoracic, and cranial vasculature. 3D workstations are now intuitive and "user-friendly", which makes them accessible to vascular surgeons and radiologists alike. The results from our study demonstrate that these tools are mandatory in everyday practice to enhance mid-term EVAR results.

In addition to the study design (retrospective analysis of prospectively collected data), we acknowledge the following study limitations. This study reports the experience of a single high-volume center dedicated to aortic endografting. We believe that there was no bias in our inclusion criteria for EVAR during the study period because our experience with custom-made fenestrated and branched aortic endografts (FEVAR) started in 2005. Thus, during the study period, all patients with unfavorable infrarenal neck anatomies had either open repair or FEVAR if they were deemed unfit for open surgery. We have strictly followed the anatomical inclusion criteria for infrarenal standard EVAR reported by the European Society for Vascular Surgery guidelines and Chaikof et al.[4] and Moll et al.[19]

In conclusion, the routine use of 3DWS for EVAR planning significantly reduces the rate of type 1 endoleaks. Access to these workstations is mandatory to enhance current results of EVAR.

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None.

CONFLICT OF INTEREST

Stéphan Haulon is a consultant for Cook Medical.

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